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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/471,622	06/05/1995	WILLIAM D. HUSE	P-IX-1613	8720

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/16/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/471,622

Applicant(s)
Huse

Examiner
John Ulm

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 30, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 16-32, 66-75, and 77 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 16-32, 66-75, and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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1) Claims 1 to 5, 7, 16 to 32, 66 to 75 and 77 are pending in the instant application. Claims 66 and 71 have been amended as requested by Applicant in Paper Number 33, filed 30 August of 2001.

2) Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 30 August of 2001 has been entered.

3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) The instant specification does not comply with 37 C.F.R. § 1.84(U)(1) for those reasons of record in section 4 of Paper Number 28. Correction is required.

6) Claims 1 to 5, 7 and 77 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 6 of Paper Number 24 and section 5 of Paper Number 28. There is no evidence of record that pVIII has ever been expressed on the surface of a cell by employing

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those techniques which were available to an artisan on 28 September of 1990. Applicant is advised that neither the periplasm nor the inner membrane of a gram negative cell constitutes the “surface” of that cell. Only the outer surface of the outer membrane of a gram negative cell would be considered by a reasonable artisan to be the surface of that cell. Applicant’s reliance on the Alberts et al. publication is misplaced. This reference specifically describes the proteins presented in Figure 13-48 as “periplasmic receptor proteins”. Even if Alberts et al. intended to identify these proteins as cell surface receptors, such identification would not be accepted because Figure 13-48 clearly shows that these receptor proteins are not expressed on the surface of a cell because no part of those receptors extends beyond the inner surface of the outer membrane.

Applicant has asserted that Figure 1 of the Marvin et al. publication demonstrates the expression of pVIII on a cell surface via membrane anchoring as well as via the attached phage particle. This figure does not illustrate the expression of pVIII on the surface of a cell via membrane anchoring. It clearly shows that pVIII is expressed in the periplasmic membrane. Second, for the purposes of the instant invention, this reference does not show the expression of pVIII on a cell surface via the attached phage particle. A critical element of the disclosed invention is the requirement that the pVIII fusion protein of the instant invention be physically attached to the DNA encoding it (“functionally linked to expression elements”, page 7, line 9 of the specification). If the DNA encoding the fusion protein of the instant invention can not be recovered by capitalizing on the ability of the fusion protein encoded thereby to bind a desired target molecule followed by the recovery of the DNA from the purified protein/DNA complex

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then the invention does not work. The only phage which are attached to the surface of the cell in Figure 1 of the Marvin et al. publication are those which have become attached, which disintegrate upon injection of the viral nucleic acid into the cell, and those which are being extruded from the cell. In either instance, the phage will not be attached to the surface of the cell for the purposes of the instant invention since the pVIII fusion protein of the instant invention is actually present on the surface of the phage particle (page 7, line 13 of the specification) and is “functionally linked to expression elements” contained within the phage particle and which “expression elements” are not present in the cell to which that phage may become attached. At no point during the practice of the instant invention can one recover a cell containing a nucleic acid encoding pVIII fusion protein of the instant invention by affinity purifying a cell expressing that fusion protein on its surface because those phage particles which have become attached to the cell rapidly disintegrate, thereby shedding the pVIII on their surfaces. Any phage particle which is being produced by the cell is rapidly extruded from the cell and does not remain attached thereto for the purposes of the instant invention since one can not isolate that cell based upon the affinity of the pVIII fusion produced thereby for a target molecule.

7) Claims 1 to 4, 7, 16 to 19, 21 to 29, 31, 32, 66 to 75 and 77 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the production of first and second DNA sequences encoding the functional portions of any “heteromeric receptor” protein other than the variable heavy and variable light chains of an antibody or T cell receptor molecule, or for the production of a vector comprising sequences “necessary” for the expression of any

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other “heteromeric receptor” protein on the surface of a filamentous bacteriophage for those reasons of record in section 7 of Paper Number 24 and section 6 of Paper Number 28. This rejection is based upon the factually supported premise that immunoglobulins and those T cell receptors which are members of the immunoglobulin superfamily are not functionally and structurally representative of the genus of proteins encompassed by the limitation “heteromeric receptor”, as explained on pages 3 to 5 of Paper Number 28 and as demonstrated by Figure 2 of the Nakanishi publication. Applicant has been provided with both evidence and sound scientific reasoning as to why the performance of immunoglobulins in the instant invention would not be accepted by one of ordinary skill in the art of molecular biology as predictive of what one could expect from members of heteromeric receptor families such as the ligand-gated ion channels. Applicant has failed to provide either evidence or scientific reasoning to the contrary. Applicant’s argument that “transmitter receptors” are functionally excluded from the limitation “heteromeric receptors” is completely in conflict with the text on page 5 of the instant specification, which expressly states that the term “heteromeric receptor” includes “proteins composed of two or more subunits” and “transmitter receptors”. This text was brought to Applicant’s attention in the previous office action. Applicant is advised that any further arguments which clearly ignore the express teachings of the instant application, and particularly those teachings which have been specifically brought to Applicant’s attention, will not serve to advance the prosecution of the instant application.

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8) Claims 70 and 75 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 7 of Paper Number 28. Applicant's has traversed this rejection essentially for those reasons of record which have been answered.

9) Claims 70 and 75 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record.

10) Claims 1 to 5, 7, 16 to 32, 66 to 75 and 77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 8, 16 to 21 and 23 to 33 of copending Application Number 08/349,131, now claims 1 to 32 of U.S. Patent Number 5,871,974, for those reasons of record in section 9 of Paper Number 12. Applicant has conceded that the pending claims are encompassed by the patent claims. Applicant urges that a species is not always obvious in view of a genus encompassing it. Such arguments are irrelevant in relation to an obviousness-type double patenting rejection, as explained in the recent CAFC decision attached hereto.

11) Applicant's arguments filed 30 August of 2001 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800